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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,282	06/18/2002	D. Laksen Sirimanne	END-5247USPCT	2605
21984 7590 06/22/2010 WELSH & FLAXMAN LLC 2000 DUKE STREET, SUITE 100 ALEXANDRIA, VA 22314				
EXAMINER				
WEATHERBY, ELLSWORTH				
ART UNIT		PAPER NUMBER		
3768				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/869,282

Applicant(s)

SIRIMANNE ET AL.

Examiner

ELLSWORTH WEATHERBY

Art Unit

3768

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 June 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 237-250 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 237-250 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date: _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☒ Other: Robinson

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 06/15/2010 has been entered.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 237-250 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 90-94, 97-99, 101-137, 154-159 and 166-168 of copending Application No. 10/960,622. Although the conflicting claims are not identical, they are not patentably distinct from each other because they claim substantially the same subject matter of a device and a method of using the device that comprises a bioabsorbable filler with a detectable marker at the center of the body, where the marker can be a wire, radiopaque or echogenic. Although the present invention and the '622 application differ in that the present invention teaches a that the second material comprises unitary piece of metal and the '622 application teaches a wire. The examiner stands that one of ordinary skill in the art would recognize that similarity and interchangeability between a wire and a unitary piece of metal.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

4. Claim 237-250 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7, 22-24, 31, 33, 111-123 of copending Application No. 09/805,652. Although the conflicting claims are not identical, they are not patentably distinct from each other because both teach a device for implanting a marker device comprising a metallic marker and a bioabsorbable or porous filler body. Because of the extent of overlapping subject matter, the Examiner stands that it would be obvious to one of ordinary skill in the art to recognize that

biocompatible suture-type material with a metallic marker disposed therein would be an equivalent to the subcutaneous marking device of claim 1, for example, comprising at least two implantable bodies it would have been obvious to have provided at least two bodies.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

5. Claims 237-250 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 77-97 and 100-104, 107-110 of copending Application No. 10/114,712. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim substantially the same subject matter comprising a marker that comprises a bioabsorbable filler with a detectable, where the marker can be a wire, metallic, and/or radiopaque. Although the 10/114,712 application does not expressly disclose an apparatus deploying the marker, it would have been obvious to one of ordinary skill in the art who is in possession of a marker to deploy the marker using any known elongate puncture or catheter device.

6. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

7. Claims 237-250 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2 of copending

Application No. 10/961,979. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim substantially the same subject matter comprising a marker that comprises a bioabsorbable filler with a detectable, where the marker can be a wire, metallic, and/or radiopaque.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

8. Claims 237-250 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 10/961,581. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim a device or method for inserting a marker in the body where the marker comprises at least one material. The present invention claims that the marker device comprises two materials and the '581 application claims introducing into the first material the second material (e.g. claims 14-15). The examiner stands that any differences comprise mere obvious variations easily recognizable by one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

9. Claims 237-250 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 11/241,500. Although the conflicting claims are not identical, they are

not patentably distinct from each other because both claim a device or method for inserting a marker in the body where the marker comprises at least one material including bioabsorbable material and a metallic material. The present invention claims that the marker device comprises two materials, a suture type bioabsorbable material and the '581 application claims a collagenous first material and a metallic second material (e.g. claims 3-4). The examiner stands that any differences comprise mere obvious variations easily recognizable by one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 237-250 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of copending Application No. 11/283,310. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim a device or method for inserting a marker in the body where the marker comprises at least one material including bioabsorbable material and a metallic material. The present invention claims an insertion device and that the marker device comprises two materials, a suture type bioabsorbable material and the '310 application claims the insertion device and a bioabsorbable matrix and a radiographically detectable second material (e.g. claims 1-4). The examiner stands that any differences comprise mere obvious variations easily recognizable by one of ordinary skill in the art.

11. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

12. Claim 244 and 250 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-39 of copending Application No. 10/960,618. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim a marking device to be inserted the body where the marker comprises at least one material. The present invention claims that the marker device comprises a bioabsorbable suture and a metal and the '618 application claims a detectable marker suspended in a bioabsorbable filler body. The examiner stands that any differences comprise mere obvious variations easily recognizable by one of ordinary skill in the art.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

13. Claim 237-250 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 11-15, 17, 26-39, 43-61, 65-80, 87, 90-102 of U.S. Patent No. 6,371,904. Although the conflicting claims are not identical, they are not patentably distinct from each other because they claim substantially the

same subject matter of a device and a method of using the device that comprises a bioabsorbable filler with a detectable marker that comprises metal.

14. Claim 237-250 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-15, 18-26, 29-42, 84-111 of U.S. Patent No. 6,356,782. Although the conflicting claims are not identical, they are not patentably distinct from each other because they claim substantially the same subject matter of a device and a method of using the device that comprises a bioabsorbable filler with a detectable marker that comprises metal.

15. Claims 244-250 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 7,668,582. Although the conflicting claims are not identical, they are not patentably distinct from each other because both claim a two component biocompatible marker. Although the present application claims a bioabsorbable suture material and the '582 patent claims a gelatin, the examiner stands that any differences are obvious variations easily recognizable by one of ordinary skill in the art.

Claim Rejections - 35 USC § 112

16. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claims 237-238, 244 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Regarding claim 237, there is not antecedent basis for the limitation, "the cannula". Accordingly, the examiner is unable to determine what structural limitations are included by the limitation. For the purposes of Examination, the cannula is being interpreted to refer to the elongate member having a distal portion and a proximal portion. Further regarding claim 237, the examiner is unable to determine what structural limitation is set forth by suture-type material. That is, it is not clear whether suture-type refers to the geometric shape of the material or the type of material, e.g. polymer, collagen, metallic wire etc. For the purposes of examination the Examiner stands that a suture type of material may refer to either the shape or the type of material. Further regarding claim 237, the claim language is unclear with regard to the second component. That is, it is not clear whether or not the "formed from a unitary piece of metal" is describing the structure of the second component or if "formed from a unitary piece of metal" is functional language describing how one makes the second component. Regarding claims 238, 244 and 250, it is not clear what structural limitation has been set forth by the limitation, "...includes multiple passes of the suture-type material forming a body". Further regarding claim 238, it is not clear whether or not "forming a body" is referring to the body set forth in claim 237 or a new body in addition to the body set forth in claim 237. Appropriate correction is required.

Claim Rejections - 35 USC § 103

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claim 237-240, 241-246, 248-250 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fulton et al. (Pub. No.: 2002/0058883) in view of Robinson et al. (Biocompatibility of Compressed Collagen Foam Plugs).

20. Fulton teaches a Biopsy Localization method and device (Abstract; Figs. 1-7). Here, Fulton teaches an elongate member having a distal portion and a proximal portion, the distal portion of the elongate member configured to seat the marking device and advance the marking device with the distal portion to the target site (0022; See: Figs. 3-7: e.g. a TrueCut type biopsy needle, a needle, or rotational vacuum assisted biopsy probe); an ejector coupled to the elongate member, said ejector configured to disengage the marking device from the distal portion (See: Figs. 3-7 as noted above); a marking device preloaded and in contact with the elongate member distal portion interior walls, for delivery through the distal portion (Abstract; 0007); wherein the marking device comprises a first component (e.g. collagen), where the first component is a bioabsorbable suture-type material (0007-0008; 0029; 0033: Here, the Examiner stands that collagen sutures are well known to one of ordinary skill in the art at the time

of the invention); and the second component is a marker, wherein the second component is carried by the first component (0028).

21. Fulton does not expressly teach that the marker is formed from a unitary piece of metal. However, the examiner stands that Fulton's disclosure, "For the device to be detected by mammography, it would have to be radiopaque and probably contain iodine or other radiopaque material (re-sorbable or not re-sorbable)." is sufficient to anticipate that the second component is formed from a unitary piece of metal. That is, in the field of implantable devices, the obviousness of the similarities and interchangeability of wires, metals, radioactive boluses, powders, and the like that are well known to enhance the visibility or applicability of otherwise non-radiopaque or MR imaggable implants or devices would be apparent to one of ordinary skill in the art. However, Fulton does not expressly teach that the second material is metal.

22. In a related field of endeavor, Robinson et al. (hereinafter Robinson) teaches a collagen sponge placed percutaneously into the lung, pleural space, liver, kidney, and muscle with a delivery device (Abstract; Figs. 1-4). Robinson goes on, teaching an elongate member having a distal portion and a proximal portion, the distal portion of the elongate member configured to seat the marking device and advance the marking device with the distal portion to the target site and an ejector coupled to the elongate member, the ejector configured to disengage the marking device from the distal portion (Fig. 1; pg. 36-37, Materials and Methods). Robinson goes on, teaching that the collagen sponge is treated with a second component formed from metal (pg. 36-37,

Materials and Methods; pg. 36, pg. 37. In-Vivo experiments: Here, the examiner notes that the metal make take any shape suitable for its intended use).

23. As state above, in the field of implantable devices, the obviousness of the similarities and interchangeability of wires, metals, radioactive boluses, powders, and the like that are well known to enhance the visibility or applicability of otherwise non-radiopaque or MR imagable implants or devices would be apparent to one of ordinary skill in the art. Therefore, the examiner stands it would have been obvious to one of ordinary skill to modify the detectable and bioabsorbable marker of Fulton in view of the tantalum treated bioabsorbable plug teachings of Robinson. The motivation to modify Fulton in view of Robinson would have been to improve visibility or applicability of the marker using known radiopaque or MR imageable agents including the tantalum treatment of Robinson or any other biocompatible marker device known in the art.

24. Claims 240 and 247 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fulton et al. (Pub. No.: 2002/0058883) in view of Robinson et al. (Biocompatibility of Compressed Collagen Foam Plugs) as applied to claims 237 and 244 above, and further in view of McKay (USPN 5,702,449).

25. Fulton in view of Robinson teach all the limitations of the claimed invention as noted above. As noted above, the examiner stands that the obviousness of the similarities and interchangeability of wires, metals, radioactive boluses, powders, and the like that are well known to enhance the visibility or applicability of otherwise non-radiopaque or MR imagable implants or devices would be apparent to one of ordinary

skill in the art. However, the examiner notes that Fulton in view of Robinson does not expressly state that the second component is titanium.

26. As an example of knowledge readily available at the time of the invention, McKay teaches reinforced spinal implants comprising a bioabsorbable suture-type material and a second component formed of a unitary piece of metal (abstract; col. 4, ll. 42-67; Figs. 1-13). McKay goes on, teaching that the second piece of material comprises Titanium (col. 5, ll. 26-53 Figs. 9-12; claim 16).

27. The examiner stands that it would be obvious to one of ordinary skill in the art at the time of the invention to modify the bioabsorbable marker of Fulton in view of Robinson with the titanium suggested by McKay. The motivation to modify Fulton in view of Robinson with the teachings of McKay would be to exploit the advantageous biocompatibility of Titanium with bone for use in bone biopsy markings.

Response to Arguments

28. Applicant's arguments with respect to claim 06/15/2010 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLSWORTH WEATHERBY whose telephone number is (571) 272-2248. The examiner can normally be reached on M-F 8:30 a.m. - 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/EW/

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768